



Application for an

Individual National Research Service Award

PHS 416-1

Public Health Service

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FOREWORD

The PHS 416-1 instructions contain information for preparing applications for Individual National Research Service Awards (NRSAs). Individual NRSAs are available at the predoctoral, postdoctoral, and senior fellowship levels. Not all of the Institutes and Centers support all of the various NRSA fellowships. Prospective fellowship applicants should contact the probable funding Institute or Center prior to preparing an application. Information on contacts can be found in the program announcement and on page 19 of these instructions.

These instructions are formatted so that the specific instructions for completing the application appear first, followed by general information on submitting the application. The next section contains assurances, a glossary and other relevant information. Sample form pages are at the back of the booklet.

Note that this packet contains sample application forms only. Blank form pages are available separately from the applicant's office of sponsored research and the NIH Web site. Applicants are encouraged to retain these instructions for future submissions. The NIH does not distribute any software for computer generation of the application. However, the forms, in Adobe Acrobat, can be downloaded from the NIH Web site at <http://www.nih.gov/grants/forms.htm>.

Future developments in electronic transfer of applications will be published periodically in the *NIH Guide for Grants and Contracts*.

These instructions and application forms (12/98) supersede all previous editions.

Applicants should give careful attention to the instructions, because an application that fails to meet the PHS requirements may be returned. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

GrantsInfo, National Institutes of Health

The Division of Extramural Outreach and Information Resources (DEOIR), Office of Extramural Research, is the central source for general information about NIH extramural research and research training

programs, funding mechanisms, the peer review system, and application procedures. The NIH grants Web site is at <http://www.nih.gov/grants/oer.htm>. The electronic mail address is GrantsInfo@nih.gov. The phone number is (301) 435-0714.

NIH and PHS Grants Policy Statements

The NIH and PHS Grants Policy Statements are compilations of the salient features of policies and various policy issues regarding the administration of NIH and PHS grant awards. Applicants to NIH should refer to the NIH Grants Policy Statement. All other applicants should refer to the PHS Grants Policy Statement. These publications are generally available in institutional offices of sponsored research. If not available, a copy may be obtained from the NIH Web site.

NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts, a weekly publication, contains all NIH requests for applications (RFAs) and program announcements (PAs), RFAs and PAs from other PHS agencies, and vital information about NIH and PHS policies and procedures. *The NIH Guide* is available via LISTSERV e-mail. For instructions to subscribe, visit the NIH grants Web site at <http://www.nih.gov/grants/guide/listserv.htm>. The NIH Guide may also be accessed at the NIH grants Web site.

PHS estimates that it will take approximately 20 hours to complete this application. This estimate does not include time for development of the research training plan. Items such as human subjects and vertebrate animals are cleared and accounted for separately, and are therefore also not part of the time estimate. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send comments to: NIH Project Clearance Office, 6701 Rockledge Drive, MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0002). Do not send applications to this address.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Individual National Research Service Award Application Form PHS 416-1

SECTION I. PREPARING YOUR APPLICATION

A. Introduction

Use this application to apply for new and competing continuation (renewal) Individual National Research Service Awards (NRSAs) from the National Institutes of Health (NIH) and Agency for Health Care Policy and Research (AHCPR). Applications for Individual NRSA fellowships will not be accepted on other forms.

Further details on policies governing the NRSA program can be found in the current National Research Service Awards Guidelines, which are available at institutional offices of sponsored programs or equivalent offices or from GrantsInfo, Division of Extramural Outreach and Information Resources (DEOIR), National Institutes of Health, (301) 435-0714, e-mail: GrantsInfo@nih.gov. The NRSA Guidelines can also be accessed via the Internet at <http://www.nih.gov/training/nrsa.htm>.

1. Program Announcements/ Requests for Applications

A PHS agency may have program announcements (PAs) or requests for applications (RFAs) related to its research mission soliciting NRSA fellowships. The PA/RFAs are available from the sponsoring PHS agency and are issued periodically in the *NIH Guide for Grants and Contracts*. Before preparing an application, applicants should thoroughly review the pertinent PA/RFA, noting the research area(s), eligibility requirements, award provisions, and service payback provisions.

2. Authorization

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Section 487 of the PHS Act, as amended (42 USC 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the PHS's ability to review an application and to monitor the grantee's performance.

B. General Instructions

Read and follow the instructions carefully to avoid delays and misunderstandings.

In preparing the application, use English and avoid jargon. For terms not universally known, spell out the term the first time it is used, with the appropriate abbreviation in parentheses; the abbreviation may be used thereafter.

Prepare the application single-sided and single-spaced, staying within the margin limitations indicated on the form and continuation pages. The print must be clear and legible. Use standard size, black letters (see page 6) that can be clearly copied. Do **not** use photoreduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that can be photocopied; glossy photographs or other materials that cannot be photocopied must be submitted in three collated sets as an appendix.

If additional space is needed to complete any of the items, use continuation pages. Blank continuation pages are provided with the form pages for both applicant and sponsor. Identify the application

item number and title. Insert continuation pages immediately after the printed page it supports; **then number the entire application consecutively.** Do not use suffixes, such as 5a or 5b. Observe page limitations.

You may substitute computer-generated facsimiles, but they must maintain the exact wording and format of the government-printed forms, including all captions and spacing. Any deviation may be grounds for the PHS to reject the entire application.

Observe type size specifications throughout the application, or the application will be returned without review. Adherence to these type size and line spacing requirements is necessary for several reasons. No applicants should have the advantage, by using small type, of providing more text in their applications. Small type may also make it difficult for reviewers to read the application.

The application must be clear, readily legible, and conform to the following three requirements:

- 1) The height of the letters must not be smaller than 10 point;
- 2) Type density must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi;
- 3) No more than 6 lines of type must be within a vertical inch. Type requirements should be checked using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/printer combination. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. The type size used throughout the application must conform to all three requirements.

The Division of Receipt and Referral, Center for Scientific Review, has the responsibility and authority to make the final determination of legibility, which is not appealable. Further inquiries should be directed to the Division of Receipt and Referral, (301) 435-0715.

C. Specific Instructions for Applicant (Part I)

The fellowship application consists of two parts:

Part I: Applicant

Face Page, Form Pages 2-6 and Section I on the Checklist (Form Page 9), and the Personal Data Page are to be completed by the applicant.

Part II: Sponsor and Sponsoring Institution Officials

Items 9-14 on the Face Page, Items 19, 20 and 21 on Form Page 2, Form Pages 7 and 8, and Section II on the Checklist Form Page 9 are to be completed by the sponsor and sponsoring institution officials.

Both parts must be submitted together in the same envelope; otherwise, the application will be returned.

The applicant should complete Part I, including Section I on the Checklist and the Personal Data Page; then forward them to the sponsor and sponsoring institution along with these instructions and any other information required for completion and submission, **including the sealed reference letters** (see page 11). The sponsor and sponsoring institution should review the specific instructions and complete Part II, including Section II on the Checklist. The applicant should verify with the sponsor that the application has been properly completed, assembled, and paginated, and that institutional approval for use of human subjects and/or vertebrate animals has been obtained.

Individual NRSA's provide a stipend to the awardee plus a small allowance to the sponsoring institution to defray some of the awardee's training expenses. Individuals sponsored by foreign institutions also receive travel funds. The specifics are provided in the awards guidelines.

The only budget information requested in the application is the tuition and fees for courses which support the research training experience and stipend/salary information for senior fellowship applicants, Section I, letters C and D on the Checklist page. Other budget items are fixed, based on a formula or determined at time of award and the applicant need not provide any information.

1. Face Page

(Follow the character length restrictions noted on the sample Face Page-AA).

Item 1. Title of Research Training Proposal.

The title or specific area of interest must not exceed 56 characters, including spaces between words and punctuation. Choose a title that is specifically descriptive rather than general. The title should not be worded in a way that would easily be misconstrued if quoted out of context.

Item 2. Level of Fellowship. Indicate the level of fellowship requested (predoctoral, postdoctoral, senior). Postdoctoral fellowships are provided by NIH Institutes and by the Agency for Health Care Policy and Research (AHCPR). Predoctoral and senior fellowships are provided by a limited number of NIH Institutes. Therefore individuals interested in these types of awards should consult with the appropriate Institute prior to submitting an application.

Note that eligibility for a senior fellowship includes possession of a doctoral degree for at least 7 years and an established research career.

Item 3. Program Announcement (PA)/Request for Applications (RFA). If the application is submitted in response to a published PA/RFA, provide the PA/RFA number. For responses to RFAs, attach the RFA label or a facsimile to the bottom of the Face Page of the original application. The RFA label can be found under the general mailing label at the end of the forms section. If the application is not submitted in response to a PA/RFA, leave Item 3 blank.

Item 4a. Name of Applicant. Type last name followed by a comma, first name, and middle initial.

Item 4b. E-mail. Self explanatory.

Item 4c. Highest Degrees at Activation. Indicate up to three academic and professional degrees held or expected to be held on the start date of the proposed award. For foreign degrees, give the U.S. equivalent.

Item 4d. Present Mailing Address. Provide the address where you can be reached at any time before the beginning date of the requested fellowship. Changes should be reported promptly in writing.

Item 4e. Permanent Mailing Address. If the information given in Item 4d is not a permanent address, provide the address where you can

always be contacted. Changes should be reported promptly in writing. If the same as 4d, so indicate.

Items 4f to 4i. Self explanatory.

Item 4j. Citizenship. Check the appropriate box. To be eligible for a fellowship, you must be a U.S. citizen, a noncitizen national, or have been lawfully admitted to the U.S. for permanent residence by the earliest possible start date of the fellowship award. U.S. noncitizen nationals are persons born in lands that are not States but are under U.S. sovereignty, jurisdiction, or administration, e.g., American Samoa. A permanent resident must submit a notarized statement before the earliest possible start date of the award that a notary has seen the applicant's Alien Registration Receipt Card or some other verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. as a permanent resident.

Item 5. Training Under Proposed Award. List the proposed area of research training according to the Lexicon of NRSA Disciplines on page 31 of these instructions. The Lexicon indicates several major areas, each with several subcategories. Select the subcategory that corresponds to the proposed area of research training. Provide **both** the number and name of the subcategory, e.g., 013 Histology. If the Lexicon does not provide a good descriptor, use the closest subcategory from the Lexicon.

Item 6. Prior and/or Current NRSA Support (Individual or Institutional). If "Yes," refer to Item 24.

Item 7a. Dates of Proposed Award. Indicate the start and end dates of the requested support period. The earliest possible start dates and the length of NRSA support that can be provided are shown in an PA/RFA or on page 18 of these instructions, Receipt, Review and Award Schedule.

Item 7b. Proposed Award Duration. Indicate the number of months (2 digits) covered by the dates in Item 7a.

Item 8. Degree Sought During Proposed Award. Complete if applicable. Completion of the degree requirements should be coordinated with your sponsor.

Items 9 through 14 (Completed by the Sponsor). The instructions for these items are in Part II, page 12.

Item 15. Applicant Certification and Acceptance.

Read the certification language carefully. Review the assurances and certifications referenced on the Checklist in Section I as well as the NRSA Service Assurance (pages 32-33). By signing the application Face Page, the applicant certifies compliance with the assurances and certifications identified in the applicant section on the Checklist. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, the suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. Failure to sign the certification precludes the possibility of an award.

2. Form Page 2 (BB)

Item 16. Applicant's Education. List all degree programs beginning with baccalaureate or other initial professional education and licensure, such as nursing (RN). Include all dates (month and year) of degrees received or expected, in addition to other information requested.

Item 17. Applicant's Training/Employment. List in chronological order all nondegree training, including postdoctoral research training, all employment after college, and military service. Clinicians should include information on internship, residency and specialty board certification (actual and anticipated with dates) in addition to other information requested. This information is used in reviewing the application and in determining the stipend level for postdoctoral fellowships.

Senior fellowship applicants should list only employment after completion of the doctoral degree, since their stipend is determined on a different basis. Senior applicants should include education and other training as appropriate.

Item 18. Goals for Fellowship Training and Career.

Explain training goals under this fellowship and the relevance to your career goals. Identify the skills, theories, conceptual approaches, etc. that you hope to learn or enhance your understanding of during the fellowship. Describe how the proposed activities, including any research, will contribute to the achievement of these career goals.

Items 19, 20 and 21. Sponsor. To be completed by sponsor.

Item 22. Description. State the broad, long-term objectives and specific aims of the research proposal, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Do not summarize past accomplishments and avoid the use of the first person. Description must be limited to the box provided on Form Page 2 (BB). This is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description will be entered in to an NIH database (CRISP) and will become public information. Therefore, do not include proprietary or confidential information.

3. Table of Contents (Form Page 3-CC)

Self-explanatory.

4. Scholastic Performance (Form Page 4-DD)

Item 23. Scholastic Performance. Listing scholastic performance facilitates the review process. Grades must be included. Applicants for the Senior Fellowship omit this item. Predoctoral (F31) applicants must send a copy of transcripts to the PHS component once a letter of admission to the doctoral program has been received.

5. Background (Form Page 5-EE)

Item 24. Prior and/or Current NRSA Support (Individual or Institutional). Follow the instructions on the form. Promptly report any additional NRSA support received while this application is pending to the PHS awarding component to which this application is assigned. An individual cannot receive more than 5 years cumulative NRSA support (the total of all support as an NRSA trainee or fellow) at the predoctoral level and 3 years cumulative NRSA support (traineeship and fellowship) at the postdoctoral level, unless a waiver has been obtained from the PHS awarding component.

Item 25a. Academic and Professional Honors and Societies. List any honors that would reflect upon your potential for a research career and your qualifications for an NRSA fellowship. Include current memberships in professional societies.

Item 25b. Title(s) of Thesis/Dissertation(s). Self-explanatory. Applicants for Senior Fellowships omit this item.

Item 26. Dissertation Advisor or Chief of Service. If not submitting a reference from this person, explain why not.

Item 27. Concurrent Support. If you have applied or will be applying for other support that would run concurrently with the period covered by this application, include the type, dates, source, and amount.

6. Research (Form Page 6-FF)

Item 28. Research Experience

Item 28a. Summary. Summarize in chronological order your research experience, including the problems studied and conclusions. Specify which problems were theses. If you have no research experience, list other scientific experience. Do not list academic courses here. Do not exceed one page.

Item 28b. Doctoral Dissertation. Summarize, not exceeding one page. Applicants for Senior Fellowships omit this item.

Item 28c. Publications. In chronological order, list your entire bibliography, separating abstracts, book chapters, reviews, and research papers. If the list of publications cannot be accommodated within two pages, select only the most pertinent publications. For each publication, give the authors in published sequence, full title, journal, volume number, page numbers, and year of publication. Indicate if you have used another name previously. Manuscripts pending publication or in preparation should be included and identified.

Submit three collated sets of the three most significant publications (two publications for predoctoral applicants). For competing continuation applications, submit three collated sets of all publications resulting from the current NRSA period of support.

Item 29. Revised Application. All revised or amended applications must include an introduction of no more than one page. In the introduction, specify significant changes that have been made. Include additions, deletions, revisions, and any

responses to criticisms in the summary statement for the previous application. All changes should be highlighted by appropriate bracketing, indenting, or change of typography. **A revised application will be returned if no substantive revisions have been made.** Reference letters are required as part of the submitted application. The revised application replaces the prior unfunded version in the NIH administrative data system.

Item. 30. Research Training Plan.

Item 30a. Activities Under Award. By year, specify the activities (research, course work, etc.) you will be involved in under the proposed award and the percentage of time to be devoted to each activity. The percentages should add to 100 for each year. Base the percentage figures on a normal working day for a full-time fellow as defined by the sponsoring institution. Also, explain briefly activities **other than** research and relate them to the proposed research training.

Item 30b. Research Training Proposal. This section should be well formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed in collaboration with the sponsor, but it is to be **written by the applicant.**

Include sufficient information to permit an effective review without reviewers having to refer to the literature or any previous application. Brevity and clarity in the presentation are considered indicative of an applicant's approach and ability to conduct a superior project. Sections (1) through (4) of this item are **not to exceed 10 pages including all tables and figures.** Follow the format below:

- (1) **Specific Aims.** State the specific purposes of the research proposal and the hypotheses to be tested.
- (2) **Background and Significance.** Sketch briefly the background to the proposal. State concisely the importance of the research described in this application by relating the specific aims to broad, long-term objectives. **For competing continuation applications, be sure to summarize your progress under your current award.**

(3) **Research Design and Methods.** Provide an outline of:

- Research design and the procedures to be used to accomplish the specific aims;
- Tentative sequence for the investigation;
- Statistical procedures by which the data will be analyzed;
- Any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised; and
- Any courses planned which support the research training experience.

Potential experimental difficulties should be discussed together with alternative approaches that could achieve the desired aims.

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that is considered to be trade secrets or information that is commercial or financial; or information that is confidential or privileged, identify the pages in the application which contain such information by marking those paragraphs or lines containing such information with an asterisk (*) in the left-hand margin and providing the page numbers before "1. Specific Aims."

When information in the application constitutes trade secrets or information that is commercial or financial, and confidential or privileged, it is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application. If an award is issued as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

Gender and Minority Inclusion for Research Involving Human Subjects

The NIH policy is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

Address the inclusion of women and members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Use a format like the Inclusion Report Format (see page 23). Include a description of proposed outreach programs for recruiting women and minorities as participants. Provide a compelling rationale and justification for requesting any exclusions noted above. When proposing Phase III clinical trials, show whether clinically important gender or race/ethnicity differences are to be expected, and the trial should be designed to accommodate any differences (see pages 21-23).

Inclusion of Children as Participants in Research Involving Human Subjects

It is the NIH policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal

must present an acceptable justification for the exclusion (see justifications for exclusions, pages 24-25).

In the research training plan, the applicant should create a section titled "**Participation of Children.**" This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

(4) Provide **literature citations** at the end of the research proposal. Each citation must include names of all authors, titles, book or journal, volume number, page numbers, and year of publication.

(5) **Human Subjects/Vertebrate Animals.** Provide the rationale for the choice of any experimental animals or procedures involving human subjects (see pages 15-16). Also, summarize the gender and racial/ethnic composition of any human subject population.

Item 30c. Respective Contributions. Describe the collaborative process between the sponsor and the applicant in the development, review, and editing of the research training proposal described in Item 30b. Do **not** include the respective roles in accomplishing the proposed research.

Item 30d. Selection of Sponsor and Institution.

- (1) Explain why the **sponsor and institution** were selected to accomplish the research training goals.
- (2) **Doctorate or Current Institution.** Since training is expected to broaden a fellow's perspective, postdoctoral applicants requesting training at either their doctorate institution or at the institution where they

have been training for more than a year must explain why further training at that institution would be valuable. Senior applicants requesting training at their employing institution should provide a similar explanation. Ordinarily, the new training value of an environment diminishes as your association there lengthens. If you are staying at the same institution, explain briefly.

(3) **Foreign Institution.** Show that the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection should be described. If applicable, the need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.

7. Personal Data on Fellowship Applicant (Form Page GG)

Clip this form to the signed original of the application after the Checklist. **Do not duplicate.**

8. Checklist (Form Page 9-JJ) – Applicant Section

All applicants must complete Section I, Items A and B; senior applicants also should complete Item C. See form page instructions for Item D.

9. Assurances and Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the applicant on the Face Page of the application (see Section III, Other Information beginning on page 20).

Debarment and Suspension
Delinquent Federal Debt
Drug-Free Workplace

10. References

At least three completed, sealed references must be submitted with the application or it will be returned to the applicant.

The instructions on the back of the reference form tell referees to complete the form and return it in a sealed envelope to the applicant as soon as possible. Applicants should remind referees that their reports should be provided on the form and any continuation pages. Applicants are asked not to open the envelopes to ensure the confidentiality of such information. The sealed envelopes should be attached to the original application. Applicants reapplying (competing continuation or revised applications) must submit new reference forms.

References should be carefully selected. Only those individuals who can make the most meaningful comments about the applicant's qualifications for a research career should be used. The sponsor of this application cannot be counted as a reference. The sponsor's recommendation is included as part of the application (Item 36). Where possible, select at least one respondent who is not in the applicant's current department. If not submitting a reference from the dissertation advisor or chief of service, explain in Item 26. Graduate or medical school respondents are preferred over those from undergraduate schools (except for predoctoral applicants).

Request reference reports only from individuals who will be able to return them in time for submission of the application. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay. Prospective applicants should send these reference forms to the referees well in advance of the application submission date.

D. Specific Instructions for Sponsors (Part II)

The sponsor should give careful attention to these instructions. Insufficient information in Part II (Form Pages 7-9) of the application may seriously diminish the applicant's chances for funding. The sponsor also completes a portion of Part I of the application, Items 9-14 on the Face Page and Items 19, 20 and 21 on Form Page 2. Parts I and II must be submitted together. If you have any questions, contact the Division of Extramural Outreach and Information Resources (DEOIR), National Institutes of Health, (301) 435-0714, e-mail: GrantsInfo@nih.gov.

See Section I, Preparing Your Application, General Instructions (page 5) and Section II, Submitting Your Application (page 18) for further instructions.

Completing the Forms

1. Face Page

(Follow the character length restrictions noted on the sample Face Page-AA.)

Item 9. Human Subjects. If activities involving human subjects are **not planned at any time** during the proposed project period, check "No." The remaining parts of Item 9 are then not applicable.

If activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, are planned **at any time** during the proposed project period of the fellowship, check "Yes." If the activities are designated to be exempt from the regulations, insert the exemption number(s) corresponding to one or more of the six exemption categories (see pages 20-21). The remaining parts of Item 9 are then not applicable. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in the review of an application. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Training Proposal (Form Page 6) and Item 37 of the Facilities and Commitment Statement (Form Page 8). In doubtful cases, consult with the Office for Protection from Research Risks (OPRR), National Institutes of Health, Rockville, MD 20892, (301) 496-7041, Web site: <http://www.nih.gov/grants/oprr/oprr.htm>.

If the planned activities involving human subjects are not exempt, complete the remaining parts of Item 9.

Project not Previously Reviewed by the Institutional Review Board (IRB). If the proposed project involves human subjects but has not previously received an IRB review, the sponsor should have the IRB review completed before submission of the application. However, if the IRB review is unavoidably delayed beyond the submission of the application, check "Yes" and enter "Pending" at the IRB approval date. A follow-up certification of IRB approval from an official signing for the sponsoring institution must then be sent to and received by the scientific review administrator of the scientific review group. The certification must be received within 60 days after the receipt date for which the application

is submitted. This follow-up certification must include the: PHS application number, title of the project, name of applicant and sponsoring institution, Multiple Project Assurance number, date of IRB approval, and appropriate signatures.

Any modifications in the Research Training Proposal (Item 30b) or in the sponsor's Item 37 that is required by the IRB must be submitted with the follow-up certification. It is the responsibility of the sponsoring institution to submit the follow-up certification. The PHS does not guarantee that it will remind the sponsoring institution, the sponsor, or the fellow to provide this missing information. If certification of IRB approval is not received within 60 days after the application receipt date, the application will be considered incomplete and deferred to the next review cycle.

The name and address of the scientific review administrator of the scientific review group will be sent to the applicant and the business official of the sponsoring institution as soon as possible after the receipt date, usually within four weeks. To avoid delays in review, send the follow-up information directly to the scientific review administrator.

Project Previously Reviewed by the IRB. In many instances, the fellow will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption is already designated. This review or exemption designation is sufficient, provided that the IRB determines that participation of the fellow does not substantially modify the research. The appropriate grants must be identified along with their IRB review dates or exemption designation. If space is insufficient in Item 9, check "Yes," enter "Item 37," and provide the information in Item 37 of the Facilities and Commitment Statement. If the sponsoring institution has an approved Multiple Project Assurance of Compliance on file with OPRR that covers the specific activity, insert the Assurance of Compliance number and the latest date of approval by the IRB of the proposed activities. This date must be no earlier than one year before the receipt date for which the application is submitted. Check the type of IRB review in the appropriate box. This information in Items 9a and 9b and the appropriate signatures fulfill the requirement for certification of IRB approval.

Indefinite Project. If the sponsoring institution has an approved Assurance of Compliance on file with OPRR but, at the time of application, plans for the involvement of human subjects are so indefinite that IRB review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 9a. If an award is made, human subjects may not be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to the PHS awarding component.

No Institutional Assurance of Compliance. If the sponsoring institution does not have on file with OPRR an approved Assurance of Compliance, check "Yes" in Item 9 and insert "None" in Item 9b. In this case, the sponsoring institution, by the signature in Item 38, is declaring that it will comply with 45 CFR 46 (the regulations for Protection of Human Subjects) within 30 days of a specific request from OPRR.

When a year will have elapsed between the initial IRB review date certified by a Multiple Project Assurance (MPA) and the anticipated award date, awarding unit staff shall require re-review and certification prior to award.

Item 10. Vertebrate Animals. If activities involving vertebrate animals are **not planned at any time** during the proposed project period, check "No" at Item 10. The remaining parts of Item 10 are then not applicable.

If activities involving vertebrate animals are planned **at any time** during the proposed award period, check "Yes." If the sponsoring institution has an approved Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR), insert the Assurance number at Item 10b. In addition, provide the date of approval by the Institutional Animal Care and Use Committee (IACUC).

If the IACUC review is unavoidably delayed beyond the submission of the application, check "Yes" and insert "Pending" at the IACUC approval date. A follow-up verification of IACUC approval from an official signing for the sponsoring institution must then be sent to and received by the scientific review administrator of the scientific review group. The verification must be received within 60 days after the receipt date for which the application is submitted. The follow-up verification must include: the PHS application number, title of project, name

of applicant and sponsoring institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures.

Any modifications of the Research Training Proposal (Item 30b) or of Item 37 of the application required by the IACUC must be submitted with the follow-up verification. It is the responsibility of the sponsoring institution to submit the follow-up verification. The PHS does not guarantee that it will remind the sponsoring institution, the sponsor or the fellowship applicant to provide this missing information. If verification of IACUC approval is not received within 60 days after the application receipt date, the application will be considered incomplete and deferred to the next review cycle.

The name and address of the scientific review administrator of the scientific review group will be sent to the applicant and the business official of the sponsoring institution as soon as possible after the receipt date, usually within four weeks. To avoid delays in review, send the follow-up information directly to the scientific review administrator.

Project Previously Reviewed by the IACUC.

In many instances, the fellow will be participating in research supported by research project grants for which the IACUC review has been obtained. This review is sufficient, provided that the IACUC determines that participation of the fellow does not substantially modify the research. The appropriate grants must be identified along with their IACUC review dates. If space is insufficient in Item 10, check "Yes," enter "Item 37," and provide the Information in Item 37 of the Facilities and Commitment Statement.

Indefinite Project. If the sponsoring institution has an approved Animal Welfare Assurance on file with OPRR but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 10a. If an award is made, vertebrate animals may **not** be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

No Institutional Animal Welfare Assurance.

If the sponsoring institution does not have on file with OPRR an approved Animal Welfare Assurance, check "Yes" in Item 10 and insert "None" in Item 10b. In this case, the sponsoring institution, by the

signature in Item 38, is declaring that it will comply with PHS policy regarding the care and use of animals by establishing an IACUC and submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OPRR.

Item 11a. Sponsor. Name the one individual who will provide research training and be responsible for the scientific and technological direction of the project. Include office telephone and fax numbers. If sponsor can receive e-mail, enter the appropriate e-mail address. If applicable, identify cosponsor(s) in Item 13 and provide biographical and other required information as specified under the instructions for Form Page 7 (HH).

Item 11b. Proposed Sponsoring Institution.

Name the one institution that will be legally responsible for committing facilities for the applicant and financially responsible for the use and disposition of any funds awarded on the basis of this application. The address should include the street, city, state, and zip code.

Item 11c. Department, Service, Laboratory, or Equivalent. Indicate your organizational affiliation at the sponsoring institution, e.g., Department of Medicine, Materials Research Laboratory, or Social Science Institution. If the department, etc. is part of a larger component, indicate both, e.g., Section on Anesthesiology, Department of Surgery, or Division of Laboratory Medicine, Department of Medicine.

Item 11d. Major Subdivision (of which the component named in Item 11c is a part). Indicate the school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, public health. If there is no such level in the sponsoring institution, enter "None."

Item 12. Entity Identification Number and Dun & Bradstreet Number (DUNS). The Entity Identification Number (EIN) should be checked or supplied by the business official of the sponsoring institution. The EIN is assigned by the Department of Health and Human Services (DHHS) for payment and accounting purposes. If a number has not yet been assigned, enter the institution's Internal Revenue Service (IRS) employer identification number (nine digits). This number will identify the organization to which funds will be disbursed. If a Dun & Bradstreet number (DUNS) is available, it should also be checked or supplied by the business official. The DUNS number is a nine digit identification

code assigned by Dun & Bradstreet. The EIN and DUNS numbers are not applicable for fellows at Federal laboratories.

Item 13. Different Advisor/Different Training Site.

Complete if different from Item 11a and Item 11b. Include advisor's name, if other than your sponsor listed in Item 11a, and include office phone number. If there are unusual circumstances involved in the research training situation, such as field work or a degree sought from an institution other than the one in which the research training will take place, and these are not described elsewhere in the application, give a detailed description in Item 34.

Item 14. Business Official. This information is to be supplied by the business official of the sponsoring institution, including Federal laboratories.

2. Form Page 2-BB

(Complete Items 19, 20 and 21)

**3. Biographical Sketch
(Form Page 7-HH)**

Since this information is almost identical to the Biographical Sketch page in the Application for Public Health Service Grant (PHS 398), you may substitute this page. If the PHS 398 page is substituted, indicate on the Biographical Sketch the total number of publications. Place the name of the applicant in the upper right corner.

If this application involves an advisor or cosponsor who has a substantial involvement and/or critical role in the Research Training Proposal, include: a Biographical Sketch; a letter of commitment from that individual; and required information for Items 32 and 33, which is addressed below.

**4. Facilities and Commitment
(Form Page 8-II)**

Item 32. Research Support Available. In a table, list all current and pending research and research training support available to the sponsor and the applicant during the period of the proposed award. Include funding source, complete identifying number, title of the research or training program, name of the principal investigator, dates, and amount of the award.

Item 33. Sponsor's Previous Fellows/Trainees.

Give the total number of predoctoral and postdoctoral individuals previously sponsored and provide information on a representative five. State their present employing organizations and position titles or occupations.

Items 34-37. Facilities and Commitment Statement.

Complete these items (34-37) as comprehensively as possible so that a meaningful evaluation of the training environment can be made by the reviewers. Use continuation pages as needed.

Item 34. Training Plan, Environment, Research Facilities.

Describe the research training plan for the applicant. Include items such as classes, seminars, and opportunities for interaction with other groups and scientists. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career.

Item 35. Number of Fellows/Trainees to be Supervised during the Fellowship.

Indicate pre- or postdoctoral.

Item 36. Applicant's Qualifications and Potential for a Research Career.

Self-explanatory.

Item 37. Human Subjects/Vertebrate Animals Use and Description.

Individual fellowship applications are subject to the same human subjects and animal welfare policies and review considerations as research project grant applications. If this application involves these subject areas and the applicant's Research Training Proposal (Item 30b) does not provide sufficient information to respond to the following instructions, provide the necessary information. In addition, in research involving human subjects, be sure that the research design includes the appropriate gender and/or minority subject population. No response is necessary if the application does not involve these areas or sufficient information has been provided.

Human Subjects. If you have marked Item 9 on the Face Page "Yes" and designated exemptions from the human subjects regulations, provide sufficient information to allow a determination that the designated exemptions are appropriate. Research that is exempt from coverage under the regulations is discussed under Human Subjects (see pages 20-21).

Even if a fellowship application is exempt from these regulations, it must, nevertheless, address the issues of gender/race/ethnic and children composition of the subject population (see page 10).

If you have marked Item 9 on the Face Page of the application "Yes" and designated no exemptions from the regulations, address the following six points. **Although no specific page limitation applies to this section, be succinct.**

1. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the Research Design and Methods section. Describe the characteristics of the population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.
2. Identify the sources of research material obtained from individually identifiable **living** human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
3. Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the IRB has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The informed consent form, which must have IRB approval, should be submitted to the PHS only if requested.
4. Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.
6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

Vertebrate Animals. If you have marked "Yes" in Item 10 on the Face Page of the application, address the following five points. **Although no specific page limitation applies to this section, be succinct.**

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic,

and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Item 38. Official Signing for Sponsoring Institution. In signing the application, the duly authorized representative of the sponsoring institution certifies that the sponsoring institution will comply with all applicable assurances and certifications referenced in the application. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of an application, the suspension and/or termination of an award, and debarment, as well as possible criminal penalties. The signer further certifies that the sponsoring institution will be accountable both for the use of any funds provided and for the performance of the grant supported project or activities resulting from this application.

5. Checklist (Form Page 9-JJ) – Sponsoring Institution Section

The Checklist is the last page of the application. The sponsoring institution is responsible for Section II. The applicant completes Section I.

6. Assurances and Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Sponsoring Institution in Item 38 (see pages 20-29).

- Human Subjects
- Vertebrate Animals
- Debarment and Suspension
- Research Misconduct
- Civil Rights
- Handicapped Individuals
- Sex Discrimination
- Age Discrimination
- Financial Conflict of Interest

Notice of Proprietary Information

When the application contains information that constitutes trade secrets; or information that is commercial or financial; or information that is confidential or privileged, the information must be identified by asterisks (*) and page number in the Research Training Plan. The information is furnished to the Government in confidence with the understanding that it shall be used or disclosed only for evaluation of this application, provided that if an award is issued as a result of, or in connection with, the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

SECTION II. SUBMITTING YOUR APPLICATION

A. Instructions

Submit the following materials in one package:

- (1) The **original application**, single-sided, with required signatures on the Face Page and on Form Page 8. Note that the pages must be assembled in the order specified in the table of contents. The Personal Data page should be placed at the end of the original application; **it is not to be duplicated**. If appropriate, attach the RFA label provided in the application kit or a facsimile to the Face Page;
- (2) **Two exact, single-sided copies of the application**. These should be made **after** all individuals have signed the application;
- (3) **At least three sealed letters of reference** attached firmly to the Face Page of the original application; and
- (4) **Three collated sets of appendix material** with items stapled where appropriate and each marked with the name of the fellow. A summary sheet listing all items included in the appendix is helpful.

Send the application to the following address:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
SUITE 1040
6701 ROCKLEDGE DRIVE MSC 7710
BETHESDA MD 20892-7710

If express mail or courier service is used, the zip code should be changed to 20817. The telephone number is (301) 435-0715.

Secure the application and its copies with rubber bands or paper clips **only**. Mail or deliver the signed original of the application and two single-sided photocopies in one package along with the Personal Data page, appendix material, sealed references, and other required information. There may be additional instructions for submission of responses to Requests for Applications. Submit a complete application. An application will be considered incomplete and returned if the instructions were not followed or if the material presented is insufficient to permit an adequate review. Do **not** send supplementary or corrective material

pertinent to an application after the receipt date without it being solicited or agreed to by prior discussion with an appropriate PHS staff member, usually the scientific review administrator of the scientific review group.

The PHS uses the following receipt, review and award schedule:

RECEIPT, REVIEW AND AWARD SCHEDULE

Application Receipt Dates	Initial Review Dates	Earliest Possible Start Dates
April 5	June/July	Aug./Sept.
August 5	Oct./Nov.	Dec./Jan.
December 5	Feb./March	April/May

An application will be considered on time if it is received by or mailed on or before the published receipt date and a proof of mailing is provided. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark; or a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable. If the receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following work day.

The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application. **No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.**

As soon as possible after the application is received, usually within 4 weeks, the PHS will send the applicant and the business official of the sponsoring institution: the application's assignment number; the name, address, and telephone number of the scientific review administrator of the scientific review group to which the application has been assigned; and the assigned Institute contact and phone number. If this information is not received within 4 weeks of the receipt date, contact the Division of Receipt and Referral, Center for Scientific Review, National Institutes of Health, Suite 2030, 6701 Rockledge Drive, MSC 7720, Bethesda, MD 20892-7720, (301) 435-0715.

All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to PHS officials. It is inappropriate to contact consultants who serve on advisory or review committees regarding these issues.

B. The Peer Review Process

The criteria for reviewing individual NRSA fellowships focus on four main components of the application: the candidate, the sponsor/training environment, the research proposal, and the training potential. Since each application is considered on an individual basis, these four areas do not necessarily receive equal weight in the consideration of the scientific review group as reflected by the priority score. Within each of the four main areas, the following is given consideration:

Candidate: The candidate's previous academic and research performance and the potential to become an important contributor to biomedical, behavioral, or clinical science.

Sponsor and Training Environment: The quality of the training environment and the qualifications of the sponsor as a mentor within the proposed research training experience.

Research Proposal: The merit of the scientific proposal.

Training Potential: The value of the proposed fellowship experience as it relates to the candidate's needs in preparation for a career as an independent researcher.

C. Interactions Before Submission

Additional information about the PHS peer review process and grant programs can be obtained from the Division of Extramural Outreach and Information Resources (DEOIR), NIH, (301) 435-0714, e-mail address: GrantsInfo@nih.gov.

Applicants are encouraged to contact relevant Institute staff for advice in preparing an application and for information regarding programmatic areas of interest. Phone numbers for contacting Institute staff are listed below:

NATIONAL INSTITUTES OF HEALTH

Fogarty International Center	301-496-1653
National Cancer Institute	301-496-3428
National Center for Complementary and Alternative Medicine	301-435-5042
National Center for Research Resources	301-496-6023
National Eye Institute	301-496-5301
National Heart, Lung, and Blood Institute	301-435-0260
National Human Genome Research Institute	301-496-7531
National Institute on Aging	301-496-9322
National Institute on Alcohol Abuse and Alcoholism	301-443-4375
National Institute of Allergy and Infectious Diseases	301-496-7291
National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
National Institute of Child Health and Human Development	301-496-0104
National Institute on Deafness and Other Communication Disorders	301-496-1804
National Institute of Dental and Craniofacial Research	301-594-7710
National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
National Institute on Drug Abuse	301-443-2755
National Institute of Environmental Health Sciences	919-541-7723
National Institute of General Medical Sciences	301-594-4499
National Institute of Mental Health	301-443-4335
National Institute of Neurological Disorders and Stroke	301-496-9248
National Institute for Nursing Research	301-594-5968
National Library of Medicine	301-496-4621
AGENCY FOR HEALTH CARE POLICY AND RESEARCH	301-594-1447

D. Interactions After Submission

Once the assignment has been made, the applicant may request reassignment if the initial assignment seems inappropriate. Such requests should be made in writing to the Division of Receipt and Referral, Center for Scientific Review, National Institutes of Health, Suite 2030, 6701 Rockledge Drive MSC 7720, Bethesda MD 20892-7720. Although these requests will be carefully considered, the final determination will be made by the PHS.

SECTION III. OTHER INFORMATION

This section contains information on policy and additional guidance relating to submission of an individual National Research Service Award application to PHS. Refer to the Foreword for additional sources of information.

Recipient organizations must report inventions promptly to the Extramural Inventions and Technology Resources Branch, Office of Policy for Extramural Research Administration, OER, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892, (301) 435-1986. This should be done **prior** to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the applicant institution, inventor, and Federal Government in the invention.

A. Assurances and Certifications

The assurances listed below may not be applicable to your project, program, or type of sponsoring institution. Refer to the NIH or PHS Grants Policy Statement for further clarification about applicability, or contact the awarding agency.

1. Human Subjects

The DHHS regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that a sponsoring institution, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that sponsoring institutions proposing to involve human subjects in nonexempt research, file a written Assurance of Compliance with the Office for Protection from Research Risks (OPRR), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the OPRR, National Institutes of Health, Bethesda, MD 20892, (301) 496-7041, and on the NIH Web site at <http://www.nih.gov/grants/oprr/oprr.htm>.

The regulations define "human subject" as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories, are exempt from coverage by the regulations:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph(2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Investigators who conduct research involving fetuses, pregnant women, children, human in vitro fertilization, or prisoners must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR 46, which describe the additional protections required for these subjects.

No DHHS award for nonexempt research involving human subjects will be made to a sponsoring institution unless that institution is operating in accord with an approved Assurance of Compliance and provides certification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations. No award to an individual will be made unless that individual is affiliated with an assured institution that accepts responsibility for compliance with the DHHS regulations. Foreign institutions must also comply with the provisions of the regulations.

The Center of Biologics Evaluation and Research (CBER), FDA, regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies. If your work involves these areas or preclinical research which will support later work in these areas, please see the Office of Recombinant DNA Activities Web site at <http://www.nih.gov/od/orda>.

a. Research on Transplantation of Fetal Tissue

In signing the application, the duly authorized representative of the sponsoring institution certifies that if research on the transplantation of human fetal tissue is conducted, the sponsoring institution will make available for audit by the Secretary, DHHS, the physician statements and informed consents required by section 498A(b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure DHHS access to those records, if maintained by an entity other than the sponsoring institution.

b. Gender and Minority Inclusion Policy

Research involving human subjects must comply with the *NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Guidelines from NIH staff, the *NIH Guide for Grants and Contracts* (March 18, 1994, Volume 23, Number 11) or the *Federal Register* (59 FR 11146-11151).

Research Involving Human Subjects

The policy of NIH is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of the proposed outreach programs for recruiting women and minorities as participants.

Funding

Awards will not be made if the research project does not comply with this policy. In addition, awardees must report annually on enrollment of women and men, and on the race and ethnicity of research participants in the Inclusion Report Format shown on the following page.

Additional Information

In conducting peer review for scientific and technical merit, SRGs must evaluate proposed plans for inclusion of minorities and both genders, the design of clinical trials, and recruitment/outreach as part of the scientific assessment and assigned score.

Under DHHS regulations to protect human subjects from research risks, certain research areas are exempt from these regulations (Exemptions 1-6). Nonetheless, NIH-supported biomedical and behavioral research projects involving human subjects that are exempt from the human subjects regulations should still address in the study design the inclusion of women and minorities. Therefore, all biomedical and behavioral research projects involving human subjects will be evaluated for compliance with this policy. For example, research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable should also be included within the term "research involving human subjects."

Inclusion Report Format

The following definitions apply for the racial and ethnic categories.

(1) Minority Groups

A minority group is a readily identifiable subset of the U.S. population which is distinguished by either racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 defines racial and ethnic categories. NIH has chosen to use these definitions because they allow comparisons to many national databases, especially national health databases.

American Indian or Alaskan Native:

A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black, not of Hispanic Origin:

A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

(2) Majority Group

White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the

population. The terms “minority groups” and “minority subpopulations” are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

(3) Subpopulations

Each minority group contains subpopulations, which are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

c. Inclusion of Children Policy

Research involving children must comply with the “**NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects,**” issued March 6, 1998. The following excerpts provide the key policy statements. Applicants should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Web site under the *NIH Guide for Grants and Contracts* (<http://www.nih.gov/grants/guide/notice-files/not98-024.html>).

Research Involving Children

NIH policy is that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise

INCLUSION REPORT FORMAT FOR EACH STUDY

Initially: Provide the number of subjects proposed for the study according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are proposed to be included in the study.

Annually: Provide the number of subjects enrolled in the study to date, according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are included in the study.

**GENDER AND MINORITY INCLUSION
STUDY TITLE:**

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

“exempt” in accord with Section 401 (b) of 45 CFR 46 Subpart A - Federal Policy for the Protection of Human Subjects. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In the research training plan, the applicant should create a section titled “Participation of Children.” This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at the NIH will assess each application as being “acceptable” or “unacceptable” in regard to the age-appropriate inclusion or exclusion of children in the research project.

Justifications for Exclusions

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is irrelevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. Documentation of other studies justifying the exclusions should be provided. NIH program

staff can be contacted for guidance on this issue if the information is not readily available.

4. A separate, age-specific study in children is warranted and preferable. Examples include:
 - a. The relative rarity of the condition in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition);
 - b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network;
 - c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them.
5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
6. Study designs aimed at collecting additional data on pre-enrolled adult

study participants (e.g., longitudinal follow-up studies that did not include data on children).

7. Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.

Definition of a Child

For the purpose of implementing these guidelines, the following definition of a child applies:

A child is an individual under the age of 21 years.

It should be noted that the definition of child described above will pertain notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states. Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the State or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

2. Vertebrate Animals

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that sponsoring institutions proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Protection from Research Risks, establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that a sponsoring institution, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163, Web site: <http://www.nih.gov/grants/oprr/oprr.htm>.

The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

No PHS award for research involving vertebrate animals will be made to a sponsoring institution unless that institution is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured institution that accepts responsibility for compliance with the PHS policy. Foreign institutions applying for PHS awards for activities involving

vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

3. Debarment and Suspension

Executive Order 12549, "Debarment and Suspension," mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Governmentwide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Governmentwide exclusion initiated on or after August 25, 1995. DHHS regulations implementing Executive Orders 12549 and 12689, and Section 2455 of the Federal Acquisition Regulation are provided in 45 CFR 76, "Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the sponsoring institution must make the following certification (Appendix A of the DHHS regulations):

"(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals (including research personnel):

"(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

"(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

"(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

"(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default."

- (2) If the individual is unable to certify to the statements in the certification, he or she should sign the application in Item 15, on the Face Page of the application and attach an explanation to the Checklist. If the sponsoring institution is unable to make the required certification, the Official Signing for Sponsoring Institution should sign the application in Item 38 and attach an explanation to the Checklist.

4. Delinquent Federal Debt

In accordance with OMB Memorandum M-87-32, "Certification of Nondelinquency by Applicants for Federal Assistance," the individual (applicant) applying for the fellowship must certify that he or she is not delinquent on the repayment of any Federal debt before an award can be made.

Examples of Federal debt include delinquent taxes, guaranteed or direct student loans, FHA loans, business loans, and other miscellaneous administrative debts. For purposes of this certification, the following definitions of "delinquency" apply:

- For **direct loans and fellowships** (whether awarded directly to the applicant by the Federal Government or by an institution using Federal funds), a debt more than 31 days past due on a scheduled payment. Definition **excludes** "service" payback under a National Research Service Award.
- For **guaranteed and insured loans**, recipients of a loan guaranteed by the Federal Government that the Federal Government has repurchased from a lender because the borrower breached the loan agreement and is in default.

If the individual is delinquent on any Federal debt, he or she should sign the application in Item 15 on

the Face Page of the application and attach an explanation to the Checklist of the application.

Where the individual discloses delinquency on debt to the Federal Government, the PHS shall: (1) take such information into account when determining whether the prospective fellow is responsible with respect to that fellowship award; and (2) consider not making the award until payment is made or satisfactory arrangements are made with the agency to whom the debt is owed. Therefore, it may be necessary for the PHS to contact the individual before a fellowship award can be made to confirm the status of the debt and ascertain the payment arrangements for its liquidation. Applicants who fail to liquidate indebtedness to the Federal Government in a business-like manner place themselves at risk of not receiving financial assistance from the PHS.

5. Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) requires that all grantees receiving grants from any Federal agency certify to that agency that they will maintain a drug-free workplace. DHHS regulations implementing the Act are provided in 45 CFR 76, "Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a fellowship award can be made, the individual applying for the fellowship must make the certification set forth below (Appendix C of the DHHS regulations). The certification is a material representation of fact upon which reliance will be placed by the PHS awarding component. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or Governmentwide suspension or debarment.

"The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant."

6. Research Misconduct

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution

has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers" (effective on the date set forth in the final rule). Further, each covered institution must certify that it will comply with those policies and the requirements of the Final Rule.

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that:

- (a) The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
- (b) The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
- (c) The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
- (d) The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349 covering the previous year will be sent automatically to all PHS awardees by the Office of Research Integrity each January.

"Misconduct in Science" and "Research Misconduct" are defined by the Public Health Service as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, contact the Office of Research Integrity, Division of Policy and Education, Rockwall II, Suite 700, 5515 Security Lane, Rockville, MD 20852, (301) 443-5300, fax: (301) 594-0042 or (301) 445-5351.

7. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)

Before a fellowship award can be made, a domestic sponsoring institution must certify that it has filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88-352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from the Division of Extramural Outreach and Information Resources (DEOIR), National Institutes of Health, (301) 435-0714, e-mail address: GrantsInfo@nih.gov (Note: Assurance of Compliance Form HHS 690 is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and, Form HHS 680, Age Discrimination.)

8. Financial Conflict of Interest

Each institution that applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by the Final Rule, 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought."

The signature of the official signing for the sponsoring institution serves as certification that:

- (a) There is in effect at that institution an administrative process to identify and resolve conflicting financial interests of the type described in Subpart 50.605 (a) with respect to all research projects for which funding is sought from the PHS;
- (b) The institution agrees to make information available to the PHS regarding all conflicting financial interests identified by the

institution of the type described in Subpart 50.605 and how those interests have been resolved to protect the research from bias; and

- (c) The institution will otherwise comply with 42 CFR Part 50, Subpart F.

Significant Financial Interests means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (i) Salary, royalties, or other remuneration from the institution;
- (ii) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (iv) Income from service on advisory committees or review panels for public or nonprofit entities;
- (v) An equity interest which meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair value market when aggregated for the investigator and the investigator's spouse and dependent children and constitute more than a five percent ownership interest in any single entity when aggregated in the same manner; or
- (vi) Salary, royalties or other payments that are not reasonably expected to exceed \$10,000 per annum from any single entity when aggregated for the investigator and the investigator's spouse and dependent children.

However, the exclusions in paragraphs (i), (v), and (vi) shall not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome in the PHS-funded research.

There are a number of additional public policy requirements with which applicants and grantees must comply. Refer to your institution's research grant administrative office or the NIH or PHS Grants Policy Statement for additional information.

B. PHS Metric Program

Consistent with Governmentwide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Governmentwide requirements, PHS policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

C. Government Use of Information Under Privacy Act

The Privacy Act of 1974 (5 U.S.C. 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder PHS's ability to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services and outside the agency to the public as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including the Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order.

Information may also be disclosed outside the Department, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees as prescribed in Department Regulations (45 CFR 5b.2) for opinions as part of the application review/award process;
5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the sponsoring institution in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

D. Information Available to the Applicant

Under the provisions of the Privacy Act, individuals may request copies of records pertaining to their applications from the PHS component responsible for funding decisions. Individuals are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete or irrelevant. If the PHS concurs, the records will be amended.

E. Information Available to the General Public

The PHS makes information about awarded fellowships available to the public, including the title of the project, the sponsoring institution, the name of the awardee, and the amount of the award.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, irrespective of the intended use of the information. Trade secrets and commercial, financial, or otherwise intrinsically valuable information that is obtained from a person or organization and that is privileged or confidential information may be withheld from disclosure. Information which, if disclosed, would be a clearly unwarranted invasion of personal privacy may also be withheld from disclosure. Although the sponsoring institution and the individual will be consulted about any such release, the final determination will be made by the PHS. Generally available for release, upon request, except as noted above, are: all **funded** fellowship applications; pending and funded **noncompeting continuation** applications; progress reports; and final reports of any review or evaluation of an individual's performance conducted or caused to be conducted by the DHHS. Generally **not** available for release to the public are: **competing** fellowship applications (initial, competing continuation) for which awards have not been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups.

F. Recombinant DNA

The current *NIH Guidelines for Research Involving Recombinant DNA Molecules* and announcements of modifications and changes to the Guidelines are available on the Internet at <http://www.nih.gov/od/orda> or from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, MD 20892, (301) 496-9838. All research involving recombinant DNA techniques that is supported by the DHHS must meet the requirements of these

Guidelines. As defined by the Guidelines, recombinant DNA molecules are either: (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1) above.

LEXICON OF NRSA DISCIPLINES

Anatomy

010 Anatomy
013 Histology
050 Pathology
056 Experimental Pathology
150 Cell Biology
840 Embryology

Biology

091 Radiobiology
100 Entomology
120 Nutrition
152 Molecular Biology
160 Zoology
170 Botany
180 Biology
183 Developmental Biology
188 Neurobiology
195 Teratology
197 Aging Process
842 Oral Biology

Chemistry

020 Biochemistry
843 Biomaterials
910 Chemistry
911 Polymer Chemistry
913 Medicinal Chemistry
914 Organic Chemistry
915 Physical Chemistry
916 Inorganic Chemistry

Genetics

110 Genetics
844 Mutagenesis

Microbiology/Immunology

040 Microbiology
041 Bacteriology
042 Immunology
044 Mycology
047 Parasitology
048 Virology

Pharmacology

060 Pharmacology

Physics/Engineering

030 Biophysics
095 Radiation Physics
432 Biomedical Engineering
630 Environmental Engineering
920 Physics
950 Engineering

Physiology

070 Physiology
075 Reproductive Physiology
078 Endocrinology
845 Communicative Sciences
846 Physiological Optics

Psychology

700 Experimental and General Psychology
702 Psychophysics
720 Physiological Psychology and Psychobiology
730 Developmental and Child Psychology
740 Personality
750 Social Psychology
770 Clinical and Counseling Psychology
798 Community and Ecological Psychology

Social/Behavioral Sciences/

Health Services Research

400 Health Administration/Public Health
780 Education and Guidance
800 Sociology
802 Demography/Population Dynamics
830 Anthropology
835 Linguistics
880 Social Sciences and Related Disciplines
886 Economics
888 Political Science
993 Bioethics
994 Social/Behavioral Sciences

Statistics/Epidemiology/

Computer Sciences

460 Biostatistics
470 Epidemiology
847 Information Sciences
900 Mathematics
901 Statistics
904 Computer Sciences

Toxicology

900 Toxicology
961 Aquatic
962 Environmental
963 Forensic
964 Inhalation
965 Occupational/Safety

Clinical Sciences

340 Psychiatry
360 Other Clinical Medicine
410 Nursing
420 Social Work
770 Clinical Psychology

NATIONAL RESEARCH SERVICE AWARD SERVICE ASSURANCE

The NIH Revitalization Act of 1993 substantially modified the service payback requirements for individuals supported by the National Research Service Award (NRSA) program. Those changes are reflected in this revised assurance.

Section 487 of the Public Health Service Act, as amended (42 USC 288) and implementing regulations (42 CFR Part 66), requires satisfactory assurance that a prospective National Research Service Awardee in their first 12 months of NRSA postdoctoral support will meet the following service requirement. Note that predoctoral NRSA fellows or other fellows who have already had 12 months of NRSA postdoctoral support do not incur a service payback obligation.

NRSA appointments or individual awards will be governed by the service payback requirements articulated in the National Research Service Award Guidelines for Individual Awards and Institutional Grants which appeared in the *NIH Guide for Grants and Contracts*, Volume 26, Number 21, June 20, 1997, and NIH Manual Chapter 4810, as amended. These guidelines can be accessed on the NIH Web site at <http://www.nih.gov/training/extramural.htm>.

I. Service Requirement — In accepting an NRSA award to support my postdoctoral research training, I understand that my first twelve months of NRSA support for postdoctoral research training carries with it a payback obligation. I hereby agree to engage in a month of health-related research, health-related research training, or health-related teaching for each month I received an NRSA award for postdoctoral research training up to and including 12 months or, if I receive an NRSA award for postdoctoral research training for more than 12 months, I agree that the 13th month and each subsequent month of NRSA-supported postdoctoral research training will satisfy a month of my payback obligation incurred in the first 12 months. This service shall be initiated within two years after termination of NRSA support. The research or teaching shall be on a continuous basis and shall average more than 20 hours per week of a full work year.

II. Payback Provisions — I understand that if I fail to undertake or perform such service in accordance with Section I above, the United States will

be entitled to recover from me an amount determined in accordance with the following formula:

$$A = \Phi [(t-s)/t]$$

where "A" is the amount the United States is entitled to recover; " Φ " is the sum of the total amount paid to me under the initial 12 months of my postdoctoral National Research Service Award support; "t" is the total number of months in my service obligation; and "s" is the number of months of such obligation served.

Except as provided in Section III below, any amount the United States is entitled to recover from me shall be paid within the three-year period beginning on the date the United States becomes entitled to recover such amount. The United States becomes entitled to recover such amount two years after termination of my National Research Service Award support if I do not engage in acceptable service payback activities in accordance with Section I above. If I elect to engage in financial repayment before the end of the two-year period, the United States becomes entitled to recover such amount on the date of my election. Interest on the amount begins on the date the United States becomes entitled to recover such amount and is at the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates prevailing on that date. I understand that I will be allowed an initial 30-day interest-free period in which to fully pay such amount, and that I may prepay any outstanding balance after that period to avoid additional interest. I further understand that I will be subject to authorized debt collection action(s) should I fail to comply with the payback provisions of this Section II.

III. Conditions for Break in Service, Waiver, and Cancellation — I hereby understand that the Secretary of Health and Human Services:

- A. May extend the period for undertaking service, permit breaks in service, or extend the period for repayment, if it is determined that:
 1. Such an extension or break in service is necessary to complete my clinical training;
 2. Completion would be impossible because of temporary disability; or

3. Completion would involve a substantial hardship and failure to extend such period would be against equity and good conscience;
- B. May waive my obligation, in whole or in part, if it is determined that:
1. Fulfillment would be impossible because I have been permanently or totally disabled; or
 2. Fulfillment would involve a substantial hardship and the enforcement of such obligation would be against equity and good conscience;
- C. Will, in the event of my death, cancel any obligation incurred under this payback agreement.

IV. Termination Notice—Annual Report of Employment—Change of Address and/or Name — I agree to complete and submit a termination notice immediately upon completion of support. Thereafter, on an annual basis I agree to complete and submit all Payback Activities Certification forms sent to me by the Public Health Service concerning post-award activities, and agree to keep the Public Health Service advised of any change of address and/or name until such time as my total obligation is fulfilled.

V. Program Evaluation — I understand that I may also be contacted from time to time, but no more frequently than once every two years, after the termination of this award to determine how the training obtained has influenced my career. Any information thus obtained would be used only for statistical purposes and would not identify me individually.

VI. Certification — By signing the certification block on the application form, I certify that I have read and understood the requirements and provisions of this assurance and that I will abide by them if an award is made.

GLOSSARY

AHCPR. Agency for Health Care Policy and Research.

CFR. Code of Federal Regulations.

Competing Continuation Application. A request for financial assistance to extend for one or more additional budget periods a project period that would otherwise expire. Competing continuation applications compete with other competing continuation, competing supplemental, and new applications for funds.

DHHS. U.S. Department of Health and Human Services.

IC. An Institute, or Center of the National Institutes of Health.

IRB. Institutional Review Board, a committee at the sponsoring organization that is required to review and approve all nonexempt research activities involving human subjects. Without approval the applications will not normally be reviewed by the PHS.

NIH. National Institutes of Health, a component of the PHS, which is part of the DHHS.

Noncompeting Continuation Application. A request for financial assistance for a second or subsequent budget period within a previously approved project period.

NRSA. National Research Service Award, provided to individuals for research training in biomedical and behavioral research.

OPRR. The Office for Protection from Research Risks.

Payback. Requirement that the awardee engage in biomedical or behavioral health-related research and/or health-related teaching or subsequent NRSA supported research training for a period equal to the period of support received during the first 12 months of NRSA postdoctoral support, or else reimburse the Government for the NRSA funds paid the awardee during this period.

PHS. Public Health Service, a component of the DHHS.

Program Announcement (PA). A formal statement that describes and gives notice to the grantee community of the existence of a extramural research activity/interest or announces the initiation of a new or modified activity/interest or mechanism of support and invites applications on a continuing basis.

Request for Applications (RFA). An official statement which invites grant or cooperative agreement applications to accomplish a specific program purpose, indicates the amount of funds set aside for the competition, and generally identifies a single application receipt date.

Revised (Amended) Application. Resubmission of an unfunded application that has been changed significantly in response to the previous review.

Scientific Review Administrator. Health scientist administrator who manages a Scientific Review Group (SRG).

Sponsor. A designated individual responsible for providing the fellow with research training and career guidance throughout the grant award period.

Sponsoring Institution. Institution legally responsible for committing facilities for the fellowship applicant and financially responsible for the use and disposition of fellowship funds.

Summary Statement. Written record of an SRG's evaluation of a grant or fellowship application. Summary statements are automatically sent to principal investigators/applicants following the SRG's review meeting.

Second Level Review (Council). Fellowship applications are not required by law to be reviewed by the pertinent National Advisory Council; but at the NIH, they receive a second review by IC staff, which consider program relevance and the SRG's recommendation in advising the IC on funding.

SRG. Scientific Review Group or Study Section, a panel of primarily non-Federal scientific experts assembled by the PHS to provide the initial review for scientific merit of grant and fellowship applications.